

REMARKS

Claims 1-14 and 16-44 are pending. Applicants have cancelled claims 17, 20, 34, 35, 37-39, and 41-43 without prejudice. Claims 1-14, 16, 18, 19, 21-33, 36, 40, and 44 will therefore be pending upon entry of the proposed amendments.

Applicants have amended claim 18 to recite "a disorder or medical condition that is associated with neuroleptic drug-induced extrapyramidal symptoms" instead of "a disorder or medical condition that is associated with neuroleptic drug therapy." Support for this amendment can be found throughout the Specification, e.g., at page 6, lines 32-33.

Applicants have amended the structure of formula (II) in claim 21 to further clarify the location of the alkylene unit " $(CH_2)_n$ " in formula (II). Support for this amendment can be found throughout the Specification, e.g., at page 21, lines 5-18.

Applicants have deleted the phrase "at an elevated temperature" from claim 24 as suggested by the Examiner.

Applicants have amended claim 36 to recite "insomnia or sleep apnea" instead of "sleep disorders." Support for this amendment can be found throughout the Specification, e.g., at page 6, line 31.

Applicants have amended claim 40 to recite "thrombosis" instead of "thrombotic illness." Support for this amendment can be found throughout the Specification, e.g., at page 6, line 27 and page 1, lines 29-31.

Applicants have amended claim 44 to recite "diabetic complications selected from nephropathy, neuropathy and retinopathy" instead of "diabetic complications." Support for this amendment can be found throughout the Specification, e.g., at page 7, lines 5-6.

No new matter is introduced by these amendments.

Applicants acknowledge that the Examiner has allowed claims 1-14, 16, 19, 28-33, and 38.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 17, 18, 34-38, and 39-44 are rejected for failure to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph.

Applicants respectfully disagree with the grounds for the rejection, however to expedite prosecution, Applicants have cancelled claims 17, 34, 35, 37-39, and 41-43, thus rendering the rejection of claims 17, 34, 35, 37-39, and 41-43 moot.

The rejection of claims 18, 36, 40, and 44 has been met by amending claims 18, 36, 40, and 44. This is discussed in more detail below.

Claim 18

Applicants respectfully disagree with the grounds for the rejection, however to expedite prosecution, Applicants have amended claim 18 to recite “a disorder or medical condition that is associated with neuroleptic drug-induced extrapyramidal symptoms,” which the Office has indicated is enabled (Office Action, page 10).

Claim 36

The Office has stated (Office Action, page 12):

In the section of applicants' remarks devoted to showing that treatment of sleep disorders, in general, is enabled by the instant specification, only insomnia and obstructive sleep apnea are addressed. Even if the treatment of these two conditions is enabled fully by the disclosure, the full scope of 'sleep disorders' is not approached in the least.

Applicants respectfully disagree with the grounds for the rejection, however to expedite prosecution, Applicants have amended claim 36 to recite “insomnia or sleep apnea” instead of “sleep disorders.”

Claim 40

Applicants respectfully disagree with the grounds for the rejection, however to expedite prosecution, Applicants have amended claim 40 to recite "thrombosis" instead of "thrombotic illness."

As discussed previously, studies in animal models have shown that a 5-HT_{2A} receptor antagonist can be effective in the treatment of thrombotic diseases. Serotonin (5-HT) is released from activated and aggregated platelets at the site of vascular injury. Studies of sarpogrelate (MCI-9041), a selective 5-HT_{2A} receptor antagonist, have shown that it exhibits anti-thrombotic effects and have lead researchers to conclude that it is "an effective agent to treat thrombotic diseases" (Hara et al. 1991 Thrombosis and Haemostasis 66:484). In one study, sarpogrelate was found to be more effective than ticlopidine hydrochloride in the treatment of certain aspects of chronic arterial occlusive disease (Furukawa et al. 1991 J Clin Ther Med 7:1747). Moreover, studies on AT-1015, a different 5-HT_{2A} receptor antagonist, led to the suggestion that "AT-1015 is a potent and long-acting oral antithrombotic agent" in a model of arterial thrombosis (Kihara et al. 2001 Eur J Pharm 433:157).

Claim 44

The Office has stated (Office Action, page 12):

Diabetic complications are myriad, yet only two are discussed in the section of applicants' remarks devoted to showing that treatment of diabetic complications in general is enabled by the disclosure of the 5HT_{2a} receptor antagonist compounds according to the present invention. So, even if applicants' remarks are accurated and true, the full scope of 'diabetic complications' cannot possible be treated with 5HT_{2a} receptor antagonist compounds. Diabetic retinopathy and nephropathy are by no means representative of the full scope of all diabetic complications.

Applicants respectfully disagree with the grounds for the rejection, however to expedite prosecution, Applicants have amended claim 44 to recite "diabetic complications selected from nephropathy, neuropathy and retinopathy" instead of "diabetic complications."

In view of the forgoing, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 17, 18, 34-38, and 39-44 are rejected under 35 U.S.C. § 112, second paragraph for allegedly being indefinite.

Applicants respectfully disagree with the grounds for the rejection, however to expedite prosecution, Applicants have cancelled claims 17, 34, 35, 37-39, and 41-43, thus rendering the rejection of claims 17, 34, 35, 37-39, and 41-43 moot.

The rejection of claims 18, 36, 40, and 44 has been met by amending claims 18, 36, 40, and 44 as discussed above. Applicants also note that the term “extrapyramidal symptoms” is expressly defined in the Specification at page 15, lines 13-16.

In view of the foregoing, Applicants submit that a person of ordinary skill in the art reading claims 18, 36, 40, and 44 as currently amended would understand the metes and bounds of claims 18, 36, 40, and 44, which are directed to methods for the treatment of “a disorder or medical condition that is associated with neuroleptic drug-induced extrapyramidal symptoms” (claim 18); “insomnia or sleep apnea” (claim 36); “thrombosis” (claim 40); and “diabetic complications selected from nephropathy, neuropathy and retinopathy” (claim 44), respectively. Applicants submit that claims 18, 36, 40, and 44 as currently amended meet the statutory requirements of 35 U.S.C. § 112, second paragraph and respectfully request that the rejection be reconsidered and withdrawn.

Claims 24, 25, and 27 are rejected under 35 U.S.C. § 112, second paragraph because of the recitation of “at an elevated temperature” in claim 24. Applicants have deleted the phrase “at an elevated temperature” from claim 24 as suggested by the Examiner and respectfully request that the rejection be reconsidered and withdrawn.

Claim Objections

Claims 21-23 and 26 are objected to "for being illegible" (Office Action, page 17) because formula (II) "includes a '(CH₂)_n' superimposed over an 'X' (Office Action, page 17). Applicants have amended the structure of formula (II) to further clarify the location of the alkylene unit "(CH₂)_n" in formula (II) and respectfully request that the objection be reconsidered and withdrawn.

CONCLUSION

Applicants submit that all claims are in condition for allowance. Applicants respectfully request that the Examiner call the undersigned to discuss the relevant rejections if in the Examiner's view the application is not in condition for allowance.

Enclosed is a \$1,020 check for the Three Month Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No.: 13425-122001.

Respectfully submitted,

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